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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,703

12/31/2003

Rodney Alan Jue

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MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

05/15/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/749,703

Applicant(s)

JUE ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10-26 and 28-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-26, and 28-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's arguments filed 2/28/07 have been fully considered but they are not persuasive.

Claims 9 and 27 have been cancelled.

The rejection of claims 1-5, 10-16, and 20-21 under 35 U.S.C. 102(e) as being anticipated by Alitalo et al. (U.S. Patent No. 6,965,010 B2) is withdrawn in view of applicant's amendments to the claims. Alitalo et al. does not teach a sequence where position 116 of the instant SEQ ID NO: 2 is cysteine. Applicant is advised that Alitalo et al. remains prior art against the instant application as this patent claims and is entitled to priority of provisional application 60/185,205, filed 2/25/00. Applicant is denied priority to provisional application 60/135,312 and 60/177,407 as basis is not seen for any of the claims in these applications. It is further noted that 60/135,312 mutates the cysteine at position 116 to serine rather than leaving it intact as in the instant methods and that 60/177,407 does not disclose the extension at the N-terminus. The effective filing date for claims 1-7, 10-26, and 28-42 is considered to be 5/18/2000. Alitalo et al. could be reapplied if the claims are amended.

### ***Priority and Oath/Declaration***

MPEP 201.08 defines a continuation-in-part as follows.

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A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and *adding matter not disclosed* in the said earlier nonprovisional application. (*In re Klein*, 1930 C.D. 2, 393 O.G. 519 (Comm'r Pat. 1930)). The continuation-in-part application may only be filed under 37 CFR 1.53(b). The continuation-in-part application must claim the benefit of the prior nonprovisional application under 35 U.S.C. 120 or 365(c). >For more information on claiming the benefit of a prior nonprovisional application, see MPEP § 201.11.<

Claims 1-42 are the originally filed claims in the instant application. Applicant argues that this application is a divisional application or at least a continuing application of 09/575,199. However, parent application 09/575,199 was filed with claims 1-74. Present claims 1-42 do not correspond identically to any originally filed claim in 09/575,199. There is some similarity to claims 35-64 of this parent application. Applicant has provided Appendix A in support of their argument that the claims filed in this application on 12/31/03 have support in the originally filed specification and claims of parent 09/575,199. This is not agreed with. The claims filed on 12/31/03 add matter not disclosed in the earlier application.

As stated in the prior Office action, there is no disclosure in 09/575,199 specifying that removal of the N-terminal sequence is performed by diaminopeptidase enzymatic digestion (see instant claim 8). Appendix A points to claims 51 and 60 of 09/575,199. These claims do not disclose diaminopeptidase enzymatic digestion. Appendix A also points to paragraph [0094] of 10/749,703. The paragraphs of the instant specification are not numbered. It is assumed that applicant meant paragraph [0094] of US 2004/0241800 A1 which is the pre-grant publication

corresponding to 10/749,703. This paragraph discloses aminopeptidases generally but does not disclose diaminopeptidases.

Claims 9 and 27 are now cancelled. However, their basis must still be considered as they were also filed on 12/31/03. As set forth in the prior Office action, there is no disclosure in 09/575,199 that specifies that 95% of VEGF dimers are devoid of an N-terminal methionine residue when the amino acid sequence is extended by a Met-(AA)<sub>n</sub> sequence at the N-terminus (see instant claim 9). Appendix A points to paragraph [0140]. This paragraph is the characterization of a particular product having a particular level of glycosylation. It is also in CHO (mammalian) rather than bacterial cells (see for example, claim 9 as it depends on claim 1). It does not demonstrate contemplation of the generic concept now claimed.

For these reasons, the instant application as filed added matter not disclosed in the earlier application and is properly a continuation-in-part. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Applicant is requested to update the continuing information in the first line of the specification and correctly identify the instant application as a continuation-in-part.

At least the limitations discussed above lack antecedent basis in the specification. Applicant is reminded that the specification is required to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Applicant is again advised that this application **as filed** remains a continuation-in-part of the parent application even if the instant claims are amended to correspond to those of the parent application.

Applicant is denied priority to parent application 09/575,199 for claims 8, 9, and 27 (it is noted that claims 9 and 27 are now cancelled) as basis is not seen for these claims in the parent application.

***Claim Rejections - 35 USC § 112***

Claims 1-8, 10-26, and 28-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record.

Applicant points to Gibbs et al. (1996); however, this reference is not of record and was not provided. Applicant's argument cannot be addressed.

Applicant's response did not address the fact that SEQ ID NO: 2 of the instant application has His at amino acid position 116 (not cysteine) and has Pro at amino acid position 75 (not Asn or Glu).

As set forth in the prior Office action, the specification does not give clear guidance as to what VEGF dimers within the scope of the claims should be produced and how to do this.

Claims 1-8, 10-26, and 28-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8, 10-26, and 28-42 refer to the amino acids of SEQ ID NO: 2. As set forth in the prior Office action, this is confusing as SEQ ID NO: 2 does not have Cys at amino acid position 116. It has His.

Claim 24 also remains unclear for the recitation of "Asn-to-Glu amino acid substitution at position 75 of SEQ ID NO: 2." SEQ ID NO: 2 does not have Asn or Glu at this position. It has Pro.

Claim 42 remains confusing in reciting "produce desired mixture of dimers." There is no antecedent basis for producing multiple varieties of dimers or in particular mixtures.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712.

The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Marianne P. Allen  
Primary Examiner  
Art Unit 1647

5/10/07

mpa